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## **Advancing Neuroscience: MRI Interventions, IMRIS and Tocagen Combine Technologies to Precisely Deliver Potential Cancer-Fighting Drug to Brain Tumors**

**First Combination of ClearPoint<sup>®</sup> Neuro Intervention System within VISIUS<sup>®</sup> Surgical Theatre to Achieve Real-Time MRI-Guided Delivery of Investigational Gene Therapy Drug Toca 511 Highlights Collaboration among Three High-Tech Healthcare Companies to Deliver Novel Therapy**

IRVINE, CA, May 30, 2013 /CNW/ - MRI Interventions, Inc. (OTCQB:MRIC) and IMRIS Inc. (NASDAQ: IMRS; TSX: IM) ("IMRIS") today announced that a surgical team at a leading U.S. neuroscience institution has delivered the investigational gene therapy drug Toca 511 directly into a glioblastoma brain tumor using real-time intraoperative MRI (iMRI) guidance within an IMRIS VISIUS<sup>®</sup> Surgical Theatre. MRI Interventions' ClearPoint<sup>®</sup> Neuro Intervention System served as the navigation platform and the ClearPoint SmartFlow<sup>®</sup> large-bore cannula as the vehicle for delivery of the therapeutic agent.

The procedure performed in early May marks the first convergence of these technologies - Toca 511, the VISIUS Surgical Theatre, and the ClearPoint System - in a unique collaboration allowing surgeons to visually monitor and confirm delivery of the desired amount of the potentially cancer-fighting drug precisely to the target location in the patient's brain within a state-of-the-art operating room designed for patient safety and efficiency.

VISIUS Surgical Theatres feature a high-field iMRI that travels on-demand between two operating rooms on ceiling rails for diagnostic and surgical usage. The multi-disciplinary suite provides truly intraoperative imaging as it does not require the patient to be moved from the OR table for scanning during surgery, so optimal positioning for neurosurgery is not compromised and typical clinical workflow is not impacted.

The ClearPoint System is the only navigation platform designed to permit real-time, direct visualization during minimally-invasive neurosurgical procedures by utilizing the powerful imaging capabilities of MRI. Surgeons use the ClearPoint System to plot a neurological

target, plan the optimal trajectory to the target, and monitor the placement of surgical tools and devices in real time throughout the operation. The ClearPoint System then provides immediate visual confirmation of the results of a procedure.

The ClearPoint System also features the SmartFlow large-bore cannula for drug delivery, which is designed to prevent reflux and leakage of a therapeutic agent outside of the target area. The SmartFlow large-bore cannula has demonstrated an ability to increase drug delivery rates by up to three times the delivery rate allowed with the original SmartFlow cannula.

Using the VISIUS Surgical Theatre's iMR imaging in conjunction with the ClearPoint System's guidance software and ClearPoint MR-compatible components, neurosurgeons are able to visually differentiate tumor tissue from healthy brain tissue, establish the target location for delivery of the therapeutic agent, and visualize delivery of the therapy in real time.

"We believe the key to drug delivery in the brain is the precise delivery of the therapeutic agent with immediate visual confirmation of results, to ensure that the full potential of the therapy is measured without apprehension over whether the drug hit its target," said Kim Jenkins, CEO of MRI Interventions. "With ClearPoint and real-time MR imaging, the surgeon can know that the drug hit its target. We look forward to continuing our work with Tocagen and IMRIS at select clinical trial sites to develop and optimize the natural synergy of these technologies."

IMRIS CEO David Graves said that these technologies working together illustrate the benefits of providing imaging at the point of therapy delivery. "This kind of therapy represents the future of neurosurgery and it is enabled by the VISIUS Surgical Theatre platform where exact targeting and delivery of focal therapies can be visualized as they happen."

In addition to drug delivery, the combination of ClearPoint and VISIUS technologies could offer significant intraoperative advantages in neurosurgical applications including laser ablation therapy, deep brain stimulation surgery, and brain biopsy.

### **About Toca 511**

[Tocagen Inc.](#), the clinical trial sponsor, is developing the investigational drug Toca 511 (vocimagene amiretrorepvec) in combination with Toca FC (an investigational extended-release formulation of 5-FC) for the treatment of recurrent high grade glioma, including glioblastoma multiforme (GBM, Grade IV glioma), the most common and aggressive form of brain cancer. Toca 511 is a retroviral replicating vector (RRV) encoding the genetic instructions for the enzyme cytosine deaminase (CD). Toca 511 is designed to selectively infect dividing cancer cells and spread through the tumor after administration. Each patient then begins a course of Toca FC. Within infected cells, the CD enzyme converts 5-FC to the anti-cancer drug 5-FU. By producing 5-FU locally, this technology has the potential to produce much higher concentrations of 5-FU in the tumor than can be safely attained with systemic administration.

Tocagen is presently enrolling patients in its investigational Phase I clinical trials. Currently, University of California, San Francisco; University of California, San Diego; Cleveland Clinic Foundation; and Henry Ford Hospital in Detroit are enrolling patients, and additional sites are

in the process of joining this study. For more information about participating in this study, please submit an [inquiry form](#) to Tocagen.

### **About Tocagen Inc.**

Tocagen Inc. is a privately funded, clinical stage biopharmaceutical company pursuing the discovery, development and commercialization of gene therapy products for the treatment of cancer. Tocagen is initially focusing on treatments for patients with advanced cancer for whom no adequate treatments currently exist. Toca 511 & Toca FC, the company's lead investigational combination product candidate, is being evaluated in clinical trials in patients with recurrent high grade glioma (such as glioblastoma multiforme). Tocagen has received grant support from leading brain cancer foundations including, Accelerate Brain Cancer Cure ([ABC2](#)), the National Brain Tumor Society ([NBTS](#)), the American Brain Tumor Association ([ABTA](#)), and the Musella Foundation. For more information about Tocagen or Toca 511 please visit: [www.tocagen.com](http://www.tocagen.com).

### **About IMRIS**

IMRIS (NASDAQ: IMRS; TSX: IM) is a global leader in providing image guided therapy solutions through its VISIUS Surgical Theatre - a revolutionary, multifunctional surgical environment that provides unmatched intraoperative vision to clinicians to assist in decision making and enhance precision in treatment. The multi-room suites incorporate diagnostic quality high-field MR, CT and angio modalities accessed effortlessly in the operating room setting. VISIUS Surgical Theatres serve the neurosurgical, cardiovascular and cerebrovascular markets and have been selected by 54 leading medical institutions around the world.

### **About the ClearPoint SmartFlow Cannula**

The SmartFlow cannula is presently FDA-cleared for injection of cytarabine, a chemotherapy drug, to the ventricles or removal of CSF from the ventricles during intracranial procedures. Delivery of Toca 511 using the SmartFlow cannula is investigational.

### **About MRI Interventions, Inc.**

Founded in 1998, MRI Interventions (OTCQB: MRIC) is a publicly traded company creating innovative platforms for performing the next generation of minimally-invasive surgical procedures in the brain and heart. Utilizing a hospital's existing MRI suite, the company's FDA-cleared and CE-marked ClearPoint<sup>®</sup> system is designed to enable a range of minimally-invasive procedures in the brain. MRI Interventions has a co-development and co-distribution agreement with Brainlab, a leader in software-driven medical technology, relating to the ClearPoint system. In partnership with Siemens Healthcare, MRI Interventions is developing the ClearTrace<sup>®</sup> system to enable MRI-guided catheter ablations to treat cardiac arrhythmias, including atrial fibrillation. Building on the imaging power of MRI, the company's interventional platforms strive to improve patient care while reducing procedure costs and times. MRI Interventions is also working with Boston Scientific Corporation to incorporate its MRI-safety technologies into Boston Scientific's implantable leads for cardiac and neurological applications. For more information, please visit [www.MRIinterventions.com](http://www.MRIinterventions.com).

### **Forward-Looking Statements**

Certain matters in this press release may constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements often can be identified by words such as

"anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would," or the negative of these words or other words of similar meaning. Forward-looking statements by their nature address matters that, to different degrees, are uncertain and involve risk. Uncertainties and risks may cause MRI Interventions' actual results and the timing of events to differ materially from those expressed in or implied by MRI Interventions' forward-looking statements. Particular uncertainties and risks include, among others: demand and market acceptance of our products; our ability to successfully expand our sales and clinical support capabilities; our ability to successfully complete the development of, and to obtain regulatory clearance or approval for, future products, including our current product candidates; availability of third party reimbursement; the sufficiency of our cash resources to maintain planned commercialization efforts and research and development programs; future actions of the FDA or any other regulatory body that could impact product development, manufacturing or sale; our ability to protect and enforce our intellectual property rights; our dependence on collaboration partners; the impact of competitive products and pricing; and the impact of the commercial and credit environment on us and our customers and suppliers. More detailed information on these and additional factors that could affect MRI Interventions' actual results are described in MRI Interventions' filings with the Securities and Exchange Commission, including, without limitation, MRI Interventions' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 10, 2013. Except as required by law, MRI Interventions undertakes no obligation to publicly update or revise any forward-looking statements contained in this press release to reflect any change in MRI Interventions' expectations or any change in events, conditions or circumstances on which any such statements are based.

SOURCE: IMRIS Inc.

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